

### REMARKS

Claims 1-27 were pending in this application. By the present amendment, claims 2-5, 15, and 20 are amended, claims 10, 16, 17, 19, and 23-26 are cancelled, and new claims 28-33 have been added. Support for the new claims can be found throughout the specification and in the original claims. In addition, support for the term "95% sequence identity" can be found at least at page 13, line 9. No new matter is introduced by these amendments. Unless specifically stated otherwise, none of these amendments are intended to limit the scope of any claim.

After entry of this amendment **claims 1-9 and 11-15, 18, 20-22, and 25-33 are pending in this application**. Consideration of the pending claims is requested.

#### June 3, 2003 Office Communication and Telephone Clarification:

Applicants thank Examiner Collins for the courtesy of her June 20, 2003 telephone conference with their representative Debra A. Gordon, Ph.D., during which the June 3, 2003 Office Communication was discussed. In that call, the Examiner clarified that (i) she had not substantively reviewed Applicants' March 10, 2003 Response, and (ii) it was necessary for the Applicants to place arguments directed to written description rejections and enablement rejections under separate headings. In addition, Examiner Collins confirmed that arguments, claims amendments, and new claims not contained in the March 10, 2003 Amendment and Response would be permitted in this Amendment. Applicants understand that their March 10, 2003, Response has not been entered into the application file, and so amendments made in that Response are being made again here.

#### Information Disclosure Statement

Applicants further thank Examiner Collins for providing a copy of the Form 1449, filed December 8, 2000, which has been initialed and dated by the Examiner.

#### Claim Objections

Claim 1 does not recite a non-elected species; therefore the objection to claim 1 is inapposite. However, in accordance with the Examiner's suggestion, claims 2-5 have been

amended to remove references to non-elected sequences ICK2, ICN2, ICN6, and ICN7.  
Withdrawal of the claim objections is therefore requested.

Claim Rejections under 35 U.S.C. §112, 1st paragraph:

Claims 1-15, 18, 20-22 and 27 have been rejected under 35 U.S.C. §112, 1st paragraph as allegedly containing subject matter “which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the [Applicants], at the time the application was filed, had possession of the claimed invention.” Applicants traverse this rejection.

In support of this rejection, the Examiner cites the Written Description Guidelines, and asserts that the specification describes a single nucleic acid encoding a plant-cyclin dependent kinase inhibitor polypeptide. Applicants respectfully submit that, although the present claims have been restricted to claiming a single species in response to the Restriction Requirement, a full spectrum of plant cyclin-dependent kinase inhibitors is in fact disclosed: ICK2, ICN2, ICN6, and ICN7. Furthermore, a consensus sequence is provided in Figure 7. Accordingly, Applicants respectfully submit that the Guidelines do not dictate that the present claims contravene §112, ¶1.

Applicants note that the Guidelines state that, for each claim drawn to a genus, “the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics.” It is accordingly clear that an actual reduction to practice of **each and every** species within a claimed genus is not a requirement of the Guidelines. This is made explicitly clear in the materials which accompanied the Guidelines, responding to comments received in response to the draft Guidelines, wherein it is stated (with emphasis added) that “The Guidelines have been clarified to state that *describing an actual reduction to practice is one of a number of ways to show possession of the invention*. Description of an actual reduction to practice offers an important ‘safe haven’ that applies to all applications and is *just one of several ways by which an applicant may demonstrate possession of the claimed invention*.”

In the present application, Applicants note that there are sequences provided for a representative number of cyclin-dependent kinase inhibitors, illustrating an actual reduction to practice for each of these CDK inhibitors.

Further, Applicants note that Example 18 in the Training Materials that accompany the Guidelines is illustrative of the fact that, where there is an actual reduction to practice of even a single embodiment, a claim which encompasses a relevant genus may nevertheless be fully supported and adequately described.

The fact that not every species within a genus needs to be enumerated is further emphasized in MPEP 2163(II)(A)(3)(a)(ii), which states that "Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." Applicants specification, as described above, contains an explicit description of a representative number of species, and it is clearly not required that Applicants provide "individual support for each species" in the genus.

Finally, Applicants do not believe that the Examiner has established a *prima facie* case as required by MPEP 2163(III)(A), by providing reasons why a skilled person would not recognize that the Applicants had possession of the invention. At most, the Examiner has provided general allegations of unpredictability, which is not sufficient – as stated explicitly in MPEP 2163.04(I). Absent a *prima facie* case, the Examiner has not met the burden in this case to make a rejection of these claims for alleged failure of written description.

For all of these reasons, Applicants request that this rejection of claims 1 15, 18, 20 22 and 27 be withdrawn.

Applicants have also added new claims 28-33. Each of these claims complies fully with the requirements of 35 U.S.C., and their scope is fully supported by the written description of this application.

Claims 1-15, 18, 20-22 and 27 have been rejected under 35 U.S.C. §112, 1st paragraph because the specification allegedly “does not enable any person skilled in the art . . . to make and/or use the invention commensurate in scope with these claims.” Applicants traverse this rejection.

The Examiner acknowledges that the present disclosure enables one skilled in the art to readily transform a plant with a nucleic acid encoding any plant cyclin-dependent kinase inhibitor (page 6 of the Action, first full paragraph). However, the Examiner suggests that it would require undue experimentation to determine which nucleic acid to express and at what level to modify development in a transgenic plant.

Applicants respectfully submit that, although routine assays may be required in order to identify selected optimal embodiments of the claimed invention, no undue experimentation is required to practice the full scope of the invention. Applicants submit that the emphasis in this test is on “undue,” and not on “experimentation” (see *In re Wands*, 858 F.2d 731, 736-40 (Fed. Cir. 1988)). As the Examiner is no doubt aware, the determination of what is meant by “undue experimentation” has been characterized by the Federal Circuit as follows (*Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d at 1365):

[t]he test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

In the current case, any necessary experiment is merely routine, and thus not undue. It is believed that any experiment is well within the limits set by the *Genentech* court.

Applicants also remind the Examiner of MPEP 2164.02, which states “...because only an enabling disclosure is required, applicant need not describe all actual embodiments.” Though not explicitly stated in the Office action, it appears that the Examiner is requiring Applicants to

describe all actual embodiments in the current case, which is not necessary in light of the enabling disclosure provided in the specification.

For all of these reasons, Applicants request that this rejection of claims 1-15, 18, 20-22 and 27 be withdrawn.

Applicants have also added new claims 28-33. Each of these claims complies fully with the requirements of 35 U.S.C., and they are fully enabled by the application.

Claim Rejections under 35 U.S.C. §112, 2nd paragraph:

Claims 1-15, 18, 20-22 and 27 have been rejected under 35 U.S.C. §112, 2nd paragraph for allegedly reciting indefinite terms as specified below. Applicants traverse rejection of each of these claims.

Claim 1 is allegedly indefinite in the recitation of "development" of a plant. The term "development" is clearly defined in the specification, *e.g.*, at page 6, lines 4-6. Thus, one of ordinary skill in the art is apprised of the meaning of the term in the context of the claim, and the scope of the claim is not rendered unclear by this clearly defined term. Thus, Applicants request that the rejection be withdrawn.

Claims 1, 18, 22 and 27 are allegedly indefinite in the recitation of "a differentiated tissue." The Examiner recognizes that "any mature plant tissue, such as [but not limited to] leaf tissue, stem tissue, floral tissue, root tissue, etc." can be a differentiated tissue. Each of these types of differentiated tissues and all differentiated plant tissues are contemplated by the term. One of ordinary skill in the art would easily recognize a differentiated tissue in a plant. The Examiner is respectfully reminded that "[b]readth of a claim is not to be equated with indefiniteness" (MPEP §2173.04).

Claim 2 is allegedly indefinite in the recitation of "homologous to." The phrase "homologous to" is clearly defined in the specification, *e.g.*, at page 12, line 28 through page 15, line 21. Thus, one of ordinary skill in the art is apprised of the meaning of the term in the

context of the claim, and the scope of the claim is not rendered unclear by this clearly defined term. Thus, Applicants request that the rejection be withdrawn.

Claims 4 and 10 are allegedly indefinite in the recitation of “optimally aligned.” Optimal alignment of sequences is defined in detail in the specification, *e.g.*, at page 13, line 9 through page 14, line 12. Thus, one of ordinary skill in the art is apprised of the meaning of the term in the context of the claim, and the scope of the claim is not rendered unclear by this clearly defined term. Thus, Applicants request that the rejection be withdrawn.

Claim 13 is allegedly indefinite in the recitation of “modified.” While Applicants believe that the original claim was clear as written, an amendment thereto is presented herein. That amendment clarifies that “modifying development of the plant makes the plant male sterile.” It is submitted that this claim, as amended, is definite, and Applicants request that this rejection be withdrawn.

Claim 14 is allegedly indefinite in the recitation of “altered.” The Examiner recognizes that “many different petal characteristics may be altered, such as color, size, shape, number, etc.” Any petal alteration, including those identified by the Examiner, is contemplated by the term. The identification of petal alterations is well within the teaching of the prior art, and the specification clearly provides examples of altered petals, such as reduced-sized petals and missing or absent petals (see, *e.g.*, Table 1 or page 35, line 11-12). A term is not indefinite because it adds breadth to the claim (MPEP §2173.04). Thus, Applicants request that the rejection be withdrawn.

Claim 15 is allegedly indefinite in the recitation of “wherein the heterologous nucleic acid is introduced into the transgenic plant, or an ancestor of the transgenic plant by the method of claim 1.” Claim 15 has been amended to remove the allegedly indefinite language. Thus, the rejection is moot, and Applicants request that it be withdrawn.

Claim 20 is allegedly indefinite in the recitation of "derived." Claim 20 has been amended to substitute the word "obtained" for the word "derived," as suggested by the Examiner. Thus, Applicants request that this rejection of claim 20 be withdrawn.

Claim 27 is allegedly indefinite in the recitation of "to change the ploidy." The Examiner recognizes that "different types of ploidy are possible, such as hyperploidy, hypoploidy, aneuploidy, etc." Any aneuploidy (including hyperploidy and hypoploidy) is contemplated by the phrase "to change the ploidy." It is unclear what additional aneuploidy is meant by "etc." in the rejection. In any event, the determination of a change in ploidy is well within the teaching of the prior art, and the specification clearly provides examples of transformed plants having changed ploidy (see, e.g., page 31, line 27-page 33, line 6). Thus, Applicants request that the rejection be withdrawn.

Claim Rejections under 35 U.S.C. §102:

Claims 1, 8, 9, 15 and 18-21 have been rejected under 35 U.S.C. §102(b) as being allegedly anticipated by P.C.L. John, U.S. Pat. No. 5,750,862, issued May 12, 1998 ("John"). Applicants traverse this rejection.

John is cited by the Examiner as teaching a method of modifying development of plants by transforming a plant with a heterologous nucleic acid encoding the cyclin dependent kinase inhibitors WEE-1 or MIK1 (referring to column 2, lines 1-7, lines 26-30, lines 54-64; column 3, lines 28-32; column 4, line 32, lines 41-65). Applicants note that in column 4, lines 57-58, the cited patent identifies the WEE-1 and MIK1 genes as being from the fission yeast. Accordingly, these are not plant cyclin-dependent kinase inhibitors, and the reference cannot anticipate the present claims. Therefore, Applicants request that the rejection be withdrawn.

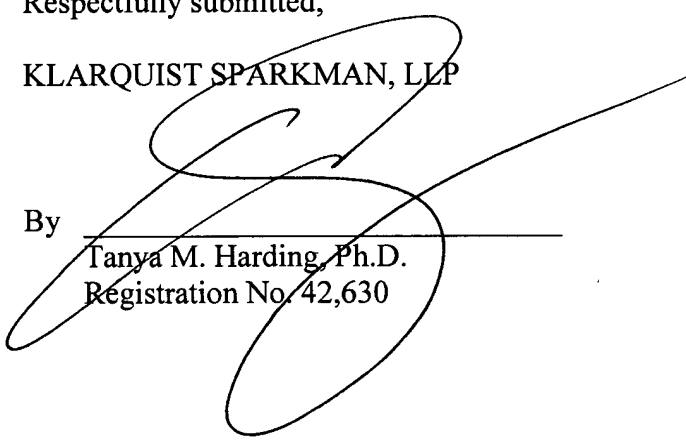
### CONCLUSION

It is respectfully submitted that the present claims are in a condition for allowance. If it may further issuance of these claims, the Examiner is invited to call the undersigned at the telephone number listed below.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By



Tanya M. Harding, Ph.D.  
Registration No. 42,630

One World Trade Center, Suite 1600  
121 S.W. Salmon Street  
Portland, Oregon 97204  
Telephone: (503) 226-7391  
Facsimile: (503) 228-9446